

Agency for Toxic Substances  
and Disease Registry  
Atlanta GA 30333

May 17, 1999

**SDMS Document ID**  
  
**2037515**

Ms. Bonnie Lavelle  
US Environmental Protection Agency  
Mail Code 8EPR-SR  
999 18<sup>th</sup> Street  
Denver, CO 80202

Re: ATSDR's procedures for maintaining confidential data

Dear Ms. Lavelle:

You requested to see ATSDR's procedures for maintaining identifiable medical information before releasing confidential biomonitoring data to ATSDR that EPA collected at the Vasquez Boulevard and I-70 site in Denver, Colorado. Those procedures are enclosed.

ATSDR's regulations state that "ATSDR shall consider only medical information in individually identified form to be confidential information and shall release such information only in accordance with the Privacy Act of 1974 (5 U.S.C. 552a) or other applicable Federal law" (42 C.F.R. § 90.12). The Privacy Act provides for the administrative, technical, procedural, and physical safeguarding of records of individuals which are maintained by a Federal agency. Also, the Freedom of Information Act (5 U.S.C. 552) specifically exempts from any disclosure "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy" or any other matters which have been "exempted from disclosure by statute." ATSDR has many years experience in protecting from public disclosure identifiable data from health studies and biological monitoring investigations.

Additionally, ATSDR has safeguards in place to protect records from inadvertent disclosure. Those safeguards involve limiting data access to authorized users and maintaining physical and procedural safeguards that are described in the enclosed document. Specifically, the confidential information that you send to ATSDR will be maintained in a locked file cabinet in a restricted access file room and building at ATSDR. Only authorized users such as myself will be allowed to use them.

If you have any questions about this issue, please feel free to call me (404-639-0639) or Ms. Paula Kocher, ATSDR's legal counsel (404-639-7205).

Sincerely,

*David Mellard*

David Mellard, Ph.D.  
Division of Health Assessment and Consultation

enclosure

cc: Paula Kocher  
Susan Muza

*Encl 1*

TABLE OF CONTENTS

AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY

PRIVACY ACT SYSTEM NOTICES

09-19-0001 Records of Persons Exposed or Potentially Exposed  
to Toxic or Hazardous Substances. HHS/ATSDR/DHS.

09-19-0001

System name: Records of Persons Exposed or Potentially Exposed to Toxic or Hazardous Substances, HHS/ATSDR/DHS.

Security classification: None.

System location: Division of Health Studies (DHS), Executive Park, Bldg. 4,  
Agency for Toxic Substances and Disease Registry, 1600 Clifton Road, NE,  
Atlanta, GA 30333.

Division of Health Assessment and Consultation, Executive Park, Bldg. 31,  
Agency for Toxic Substances and Disease Registry, 1600 Clifton Road, NE,  
Atlanta, GA 30333.

and

Federal Records Center, 1557 St. Joseph Avenue, East Point, GA 30344.

Data are also located at contractor sites. A list of contractor sites where individually identified data are currently located is available upon request to the System Manager.

Categories of individuals covered by the system: Individuals exposed or potentially exposed to toxic or hazardous substances may include the following: (1) Selected persons living or having lived near a hazardous waste site, including facilities owned or operated by the United States; (2) Persons

exposed or potentially exposed to environmental hazards resulting from ingestion of contaminated drinking water, persons exposed to contaminated soil, persons living on mining wastes, persons inhaling toxic substances (all of which may or may not be the result of contamination by a specified waste site); (3) Participants in health outcome studies (including exposure studies, symptom and disease prevalence studies, cluster investigations), and epidemiologic studies to determine the public health threat of exposure to hazardous or toxic substances; (4) Registry participants with exposures associated with specific chemicals; (5) Participants from sites of emergency activities, and other sites that are the subject of a citizen's petition; (6) Persons working or having worked in response actions at hazardous waste sites or other occupational settings where exposure to hazardous substances occurred. The first five categories of persons above may include children as well as adults.

Categories of records in the system: Name, address, (including length of time at current address), telephone number, date of birth, Social Security number, sex, current and past occupations, dates, pathways and routes of toxic or hazardous substance exposure or potential exposure, smoking history, results of medical and laboratory tests, records on biological specimens (e.g. blood, urine, etc.), and related documents such as questionnaire responses. The specific type of records collected and maintained is determined by the needs of the individual registry or study.

Authority for maintenance of the system: "Comprehensive Environmental Response, Compensation, and Liability Act of 1980" as amended by "Superfund Amendments and Reauthorization Act of 1986" (42 U.S.C. 9601, 9604); and the

"Resource Conservation and Recovery Act of 1976" as amended in 1984 (42 U.S.C. 6901).

Purpose(s): Records in this system are used to carry out the legislated environmental public health mandates of the Agency for Toxic Substances and Disease Registry (ATSDR). Specifically this information is used to: (1) identify the public health threat caused by exposure to toxic and hazardous substances utilizing health outcome studies, epidemiologic studies, and other health effects studies; and (2) establish and maintain national registries of persons exposed to toxic substances and persons with serious diseases and illnesses associated or potentially associated with exposure to toxic substances. Registries will have the additional purposes of tracking exposed individuals, keeping them informed of health effects of exposure, preventive measures and possible breakthroughs in treatment, along with serving as a centralized location for research data on these exposed individuals.

Records may be disclosed to the Center for Environmental Health and Injury Control, Centers for Disease Control and Prevention, for laboratory analysis of samples and for collaborative efforts (i.e., providing staff, performing statistical analysis, etc.) in coordinating investigations.

Records (i.e., name, Social Security number, date of birth) may be disclosed to the National Center for Health Statistics to obtain a determination of vital status. Death certificates with the cause of death will then be obtained from Federal, State, or local agencies to enable ATSDR (1) to determine whether excess mortality is occurring among individuals exposed to toxic or hazardous substances, and (2) to notify similarly exposed persons.

Records may also be disclosed to the Social Security Administration for additional sources of locating information.

Routine uses of records maintained in the system, including categories of users and the purposes of such uses:

1. Records may be disclosed to Department of Health and Human Services contractors to locate individuals exposed or potentially exposed to toxic or hazardous substances (e.g., in the establishment of the National Exposure Registry), conduct interviews, perform medical examinations, collect and analyze biological specimens, evaluate and interpret data, and perform followup health investigations so that the research purposes for which the records are collected may be accomplished. The contractor must comply with the requirements of the Privacy Act with respect to such records.
2. Records may be disclosed to Federal agencies as the Environmental Protection Agency (EPA), State and local health departments, and other public health or cooperating medical authorities in connection with program activities and related collaborative efforts to deal more effectively with exposures to hazardous or toxic substances, and to satisfy mandatory reporting requirements when applicable.
3. Records (i.e., name, Social Security number) may be disclosed to other

Federal agencies and to missing person location agencies to obtain information to aid in locating individuals involved in these studies.

4. Records may be disclosed for a research purpose, when the Department:
  - (A) has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained;
  - (B) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identified form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring;
  - (C) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written authorization of the Department, (c) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law;
  - (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these

provisions.

5. Disclosures may be made to a congressional office from the records of an individual, in response to a verified inquiry from the congressional office made at the written request of that individual.
6. In the event of litigation initiated by EPA in collaboration with ATSDR, ATSDR may disclose such records as it deems desirable or necessary to the Department of Justice to enable the Department to effectively represent ATSDR. The types of litigative proceedings that ATSDR may request include the recovery of expenses incurred in cleanup operations at Superfund or Resource Conservation and Recovery Act sites, including program and staff costs.
7. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claims, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example, in defending a claim against the Public Health Service based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, disclosure may be made to the Department of Justice to enable that Department to present an effective defense, provided that such disclosure is compatible with the purpose for which the records

were collected.

8. Records may be provided to the Social Security Administration by ATSDR, for the purpose of locating or tracking individuals, to accomplish the research or program purpose for which the records were collected.

Policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system:

Storage: File folders, computer tapes and disks (hard and floppy).

Retrievability: By name or Social Security number.

Safeguards: The following special safeguards are provided to protect the records from inadvertent disclosure:

1. Authorized Users: Access is granted to only a limited number of physicians, scientists, statisticians, and designated support staff of ATSDR or its contractors, as authorized by the system manager to accomplish the stated purposes for which the data in this system have been collected. A list of authorized users will be maintained by the system manager.
2. Physical Safeguards: Questionnaires, log books, and other source data

are maintained in locked cabinets in locked rooms, 24-hour guard service in buildings, personnel screening of visitors, electronic anti-intrusion devices in operation at the Federal Records Center (FRC), fire extinguishers, overhead sprinkler system, and card-access control equipment in the mainframe computer room (Clifton Road facility), computer terminals, lockable personal computers, and automated records located in secured areas.

3. Procedural Safeguards: Protection for computerized records includes programmed verification of valid user identification code, account code and password prior to acceptance of a terminal session or job submission, computer software to control access, frequently changed passwords, and Vault Management System.

Knowledge of individual tape passwords is required to access tapes, and access to systems is limited to users obtaining prior supervisory approval. When Privacy Act tapes are scratched, a special "certified" process is performed in which tapes are completely written over to avoid inadvertent data disclosure. When possible, a backup copy of data is stored at an offsite location and a log kept of all changes to each file and all persons reviewing the file. Selected safeguards will be applicable to specific elements of the system, as appropriate.

Additional safeguards may also be built into the program by the system analyst as warranted by the sensitivity of the specific data set.

ATSDR and contractor employees who maintain records are instructed in specific procedures to protect the security of records, and are to check with the system manager prior to making disclosure of data. When

individually identified data are being used in a room, admittance at either ATSDR or contractor sites is restricted to specifically authorized personnel.

Appropriate Privacy Act provisions are included in contracts and the ATSDR Project Director, contract officers, and project officers oversee compliance with these requirements. Upon completion of the contract, all data will be either returned to ATSDR or destroyed, as specified by the contract.

4. Implementation Guidelines: The safeguards outlined above are developed in accordance with Chapter 45-13, "Safeguarding Records Contained in Systems of Records," of the HHS General Administration Manual, supplementary Chapter PHS.hf: 45-13; Part 6, "Automated Information Systems Security," of the HHS Information Resources Management Manual; the National Bureau of Standards Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31). FRC safeguards are in compliance with GSA Federal Property Management Regulations, Subchapter B--Archives and Records.

Retention and disposal: A Comprehensive Records Control Schedule has been proposed for ATSDR at the time of this publication. Current procedures allow the system manager to keep the records for 20 years unless needed for further study. Registry records will be actively maintained as long as funding is provided for by legislation. Contractors will retain the records only as long as necessary to complete data collection and verify ATSDR's receipt of the data in usable form. Record copy of study reports is maintained in the agency

from two to three years in accordance with retention schedules. Source documents for computer tapes or disks are disposed of when no longer needed in the study in the study as determined by the system manager, and as provided in the signed consent form, as appropriate.

Records may be transferred to a Federal Records Center for storage when no longer needed for evaluation or analysis. Disposal methods include the paper recycling process, burning or shredding hard copy records, and erasing computer tapes and disks.

System manager(s) and address: Director, Division of Health Studies, Executive Park, Bldg. 4, MS E31, Agency for Toxic Substances and Disease Registry, 1600 Clifton Road, NE, Atlanta, GA 30333.

Director, Division of Health Assessment and Consultation, Executive Park, Bldg. 31, MS E32, Agency for Toxic Substances and Disease Registry, 1600 Clifton Road, NE, Atlanta, GA 30333.

Policy Coordination is provided by: Deputy Assistant Administrator, Executive Park, Bldg. 37, MS E28, Agency for Toxic Substances and Disease Registry, 1600 Road, NE, Atlanta, GA 30333.

Notification procedure: An individual may learn if a record exists about himself/herself by contacting the appropriate system manager at the above address. Persons who knowingly and willfully request or acquire a record pertaining to an individual under false pretenses are subject to criminal prosecution. Requestors in person must provide photo identification (such as

driver's license) or other positive identification that would authenticate the identity of the individual making the request. Individuals who do not appear in person must submit a request which has been notarized to verify their identity. A parent or guardian who requests notification of, or access to, a minor's medical record must provide a birth certificate (or notarized copy), court order, or other competent evidence of guardianship. An individual who requests notification of, or access to, a medical record shall at the time the request is made, designate in writing a responsible representative (who may be a physician, other health professional, or other responsible individual) who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

In addition, the following information should be provided when requesting notification: (1) full name and Social Security number; (2) nature of the study, or probable exposure or disease subregistry which might include the requester.

Record access procedures: Same as notification procedures. Requestors should also reasonably specify the record contents being sought. An accounting of disclosures that have been made of the record, if any, may also be requested.

Contesting record procedures: Contact the system manager at the address specified above, reasonably identify the record and specify the information being contested, the corrective action sought, and the reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

Record source categories: Subject individuals, families of deceased individuals, concerned citizens associated with a particular site, State and local health departments, physicians records, hospital records, Social Security Administration, Environmental Protection Agency and other agencies responsible for environmental public health.

Systems exempted from certain provisions of the act: None.

Federal Register Billing Code: 4160-70.